



Department of Health

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www.health.ri.gov

VIA ELECTRONIC MAIL

March 30, 2018

Adelita S. Orefice, Esq.
Barrett & Singal
One Cedar Street, Suite 300
Providence, RI 02903

Dear Ms. Orefice:

Attached is the final *Report of the Health Services Council on the application of The American Center for Bioregulatory Medicine and Dentistry (whose parent companies include Bioregulatory Medical, LLC, Bioregulatory Dental, LLC and Robert Woodford Enterprises, LLC) for the Initial Licensure of an Organized Ambulatory Care Facility located at 111 Chestnut Street in Providence* that was adopted by the Health Services Council on March 20, 2018.

Pursuant to RIGL 23-17 and the *Rules and Regulations for the Licensing of Organized Ambulatory Care Facilities (R23-17-OACF)*, the Rhode Island Department of Health ("RIDOH") accepts the recommendation of the Health Services Council and hereby approves the application for Initial Licensure as an Organized Ambulatory Care Facility and adopts the attached report in its entirety, including Conditions #1 through #5 identified in the attached report.

In addition, RIDOH has carefully considered this application and its unique nature. Pursuant to RIGL 23-17-14.4 (d) and in consideration of the entire record the application is subject to the additional conditions of approval as set forth below:

Assurance the staff are clinically competent and have adequate supervision.

Condition #6. The applicant shall submit the titles and duties of all employees, as well as training, credentials to RIDOH and must update RIDOH upon new hires for up to three (3) years at the discretion of RIDOH.

Condition #7. The applicant shall submit a plan of supervision for all employees and clearly state which licensed professionals provide direct supervision (i.e. in-person, co-located with the person doing the procedure) as well as a list of procedures done with indirect supervision (i.e. licensed health care practitioner is not present in the building) to RIDOH for up to three (3) years at the discretion of RIDOH.

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Assurance that patients will not receive therapies that may conflict with present therapies from the patients' primary care provider or other treating clinicians.

Condition #8. The applicant shall establish a mechanism to, with patients' permission, coordinate care with all patients' primary care providers and other specialty providers, including reporting of consultation and treatment.

Assurance that patients who undergo replacement of dental restorations are fully informed of current evidence.

Condition #9. The applicant shall obtain written consent from patients with disclaimer (attached) indicating there is currently insufficient evidence to support or refute any adverse effects associated with amalgam or composite restorations and current evidence neither supports nor refutes objective health benefits from removal of any specific restorative material and provide a copy of the disclaimer to patients.

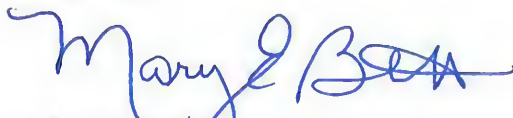
Assurance that there is no potential for deceptive advertising.

Condition #10. The applicant shall submit copies of all proposed promotional, educational or informational communications or press releases as they may relate to the Rhode Island facility for prior review and approval by RIDOH for at least three (3) years after initial licensure at the discretion of RIDOH.

Please be advised that this approval is a condition to licensure. Prior to actual licensure, the applicant must complete the attached licensure forms and submit them to the Center for Health Facilities Regulation. Upon receipt of these completed forms, this Center will initiate final licensure activities.

Please contact the Center for Health Facility Regulations at (401) 222-2566 with regards to any questions regarding the license application.

Sincerely,

A handwritten signature in blue ink, appearing to read "Mary E. Bennett".

Mary E. Bennett

Chief

Center for Health Facilities Regulation

Attachment

Disclaimer and Acknowledgement

As required by the **Rhode Island Department of Health**, the American Center for Bioregulatory Medicine and Dentistry has provided me the following information, prior to me receiving or agreeing to receive any dental restorative services (fillings), and I hereby acknowledge my full understanding of this information.

Current medical evidence neither supports nor refutes any objective health benefits derived from the removal of any specific restorative material. There is currently insufficient medical evidence supporting or refuting adverse effects associated with amalgam or composite restorations. Each removal of a filling necessitates loss of additional tooth structure, compromising the integrity of the tooth, and increasing the likelihood of need for further care.

Client Signature

Date

REPORT OF THE HEALTH SERVICES COUNCIL
ON THE APPLICATION OF
THE AMERICAN CENTER FOR BIOREGULATORY MEDICINE AND DENTISTRY, LLC,
(ITS PARENT COMPANIES BIOREGULATORY MEDICAL, LLC, BIOREGULATORY
DENTAL, LLC, AND ROBERT WOODFORD ENTERPRISES, LLC)
FOR THE INITIAL LICENSURE OF
AN ORGANIZED AMBULATORY CARE FACILITY AT
111 CHESTNUT STREET, PROVIDENCE, RI

Health Services Council

Victoria Almeida, Esq. (Chair)
John J. Barry III
Stephen Boyle
Raymond C. Coia, Esq. (Secretary)
John X. Donahue
Linda Johnson
Lisa Lasky, CPA
Robert Mancini
Jeanette S. Matrone, RN, PhD (Vice Chair)
Tarah Provencal
John Sepe

Submitted to the
Health Services Council
to Review and Adopt
March 20, 2018

Adopted by the
Health Services Council
March 20, 2018

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I. SYNOPSIS

The Health Services Council recommends that the application of the American Center for Bioregulatory Medicine and Dentistry, LLC (its parent companies Bioregulatory Medical, LLC, Bioregulatory Dental, LLC, and Robert Woodford Enterprises, LLC) for the Initial Licensure of an Organized Ambulatory Care Facility located at 111 Chestnut Street, Providence, RI be approved.

II. PROPOSAL DESCRIPTION

American Center for Bioregulatory Medicine and Dentistry, LLC (the "applicant" or "Center") is owned fifty percent (50%) by Bioregulatory Medical, LLC, and fifty percent (50%) by Bioregulatory Dental, LLC, both Rhode Island companies. Bioregulatory Medical is, in turn, owned sixty-five percent (65%) by Robert Woodford Enterprises, LLC ("RWE"), which is incorporated in Kentucky, and thirty-five percent (35%) by Jeoffrey Drobot, NMD. Similarly, Bioregulatory Dental is owned sixty-five percent (65%) by RWE and thirty-five percent (35%) by Gerry Curatola, DDS. RWE is one-hundred percent (100%) owned by Robert W. Dulaney. An organizational chart of the applicant is attached.

Dr. Gerry Curatola, DDS is a biologic restorative dentist with more than 30 years of clinical practice experience. He is the founder of Rejuvenation Dentistry, a multi-specialty integrative dental practice in New York City based on the principles of bioregulatory healthcare. Dr. Curatola will be contributing his professional expertise to the applicant.

Jeoffrey Drobot, NMD is one of the founders and medical directors of the American Center for Biological Medicine, a private practice in Scottsdale, Arizona. According to the applicant, Dr. Drobot is a leading authority in the fields of European Biological Medicine and will be contributing his professional expertise to the applicant.

Robert Dulaney is a private equity investor. Mr. Dulaney will be contributing \$3.6 million (100% equity) as start-up and operating funds for the Center through his company RWE.

Michael Baldwin will serve as a Chief Operating Officer and Administrator of the Center. He also serves as the sole Manager for RWE, co-Manager with Dr. Drobot of Bioregulatory Medical, and co-Manager with Dr. Curatola of Bioregulatory Dental. Mr. Baldwin holds no ownership share of the Center or any of its parent companies.

The Center is an incubator project facilitated by the Marion Institute. The Marion Institute is a non-profit organization founded by Michael Baldwin. The Marion Institute is also home of the Bioregulatory Medicine Network which connects practitioners, including traditional health care professionals who are interested in alternative medicine and dentistry, to each other and to the latest research and practice developments.

The proposed location of the Center is 111 Chestnut Street in Providence. Modeled on the Paracelsus Clinic in Switzerland, the proposed Rhode Island facility will provide alternative, holistic medical and dental treatment focused on identifying the root cause of illness and promoting the body's capacity for

natural healing. According to the applicant, bioregulatory (also called biologic) medicine and dentistry incorporates healing modalities, such as homeopathy, naturopathy, Chinese medicine, ayurvedic practice, and many others with respect to a patient's entire state of physical and emotional well-being.

The applicant stated it will use non-invasive and minimally invasive diagnostic tools such as:

- Bio-impedance Analysis (BIA)
- Heart Rate Variability (HRV) testing
 - Variation in the time interval between heartbeats. It is measured by the variation in the beat-to-beat interval
- Digital Pulse-Wave Analysis (DPA)
 - Non-invasive, technology-driven process that uses LED sensors
 - tool to assess arteriosclerosis and is also useful in evaluating oxygen perfusion to tissue; early detection for high blood pressure, peripheral circulatory disturbance and vessel aging status
- Computerized Regulation Thermography (CRT)
 - Non-invasive, way of evaluating the function of the major organs of the body
 - Precisely measuring skin temperatures across the body before and after exposure to cool air
 - Examining the differences in these readings gives insight into nerve signals and capillary dilation within the body and exposes potential problem areas or imbalances

Treatment therapies may include:

- exercise with oxygen therapy (EWOT)
- electron foot baths
 - uses conduction and a specific frequency to drive and shift electrons through the body while the patient sits with their feet immersed in a warm foot bath
 - healthy cells have a voltage difference between the inner and outer membrane referred to as the membrane resting potential that ranges from -70 to -90 mV. Through immune, endocrine, and nervous system support and by restoring the electromagnetic balance of the cell, the tissue is able to repair and heal
- soundbed therapy
 - acoustic therapy can balance your heart rate/blood pressure, increase circulation, reduce chronic muscle tension, energize your moods and emotions, and greatly reduce stress.
- hyperbaric oxygen treatment
 - involves breathing pure oxygen to increase the amount of oxygen your blood can carry. An increase in blood oxygen temporarily restores normal levels of blood gases and tissue function to promote healing and fight infection.
- IV nutrient therapy

- magnapulse therapy
- replacement of toxic elements such as mercury fillings and corrosive metals in dental implants with composite
- Periodontal Maintenance
 - Deep cleanings that keep your mouth fresh and healthy. Scheduled every three to four months, the visits allow the Center to clean teeth below the gum line, at the root surface.
- Dental crowns, bridges and veneers

The applicant stated it will also provide other naturopathic and holistic treatments that work with the biology of the body and its natural healing capabilities and consider the spiritual, emotional and physical aspects of disease.

The applicant will offer services seven (7) days a week, from 8:30 am to 6 pm Monday through Friday, 10:00 am to 4:00 pm on Saturday and 10:00 am to 2:00 pm on Sunday.

The Center has stated that it is committed to educating the public about the benefits of alternative therapies to traditional medicine and dentistry. Through a series of education and awareness campaigns designed for a variety of audiences, the Center hopes to attract patients who represent all parts of our community. The Mary Shands Scholarship fund is a program designed to providing access to anyone who wants to receive treatment at the center will be able to do so regardless of their ability to pay directly for the services.

The Center is not seeking accreditation, according to the applicant there is no national accrediting body for bioregulatory medicine and dental clinics.

The capital cost of the proposal is \$3,610,657 financed by 100% owner equity. The applicant expects that the Center will operate initially at a loss, but will begin earning a profit by its first full year. Projected revenue for the first full year (FY 2019), \$3,328,684 and operating expenses are anticipated to be \$2,391,131.

The bioregulatory services offered at the clinic are not covered services under Medicare or Medicaid. The applicant stated some dental services will be covered by insurance, roughly 25%. Those treatments not covered by insurance will be self-pay.

If the proposal is approved, the following payor mix projected FY 2018 will be: 0% Medicare; 0% Medicaid; 0% HMO's; 5% Blue Cross; 21% Commercial; 0% Workers' Comp; 74% Self-Pay and .7% Charity Care.

III. INTRODUCTION

Pursuant to the requirements of Chapter 23-17 of the General Laws of Rhode Island entitled "Licensing of Health Care Facilities," the applicant filed application for initial licensure to establish an Organized Ambulatory Care Facility. This request is made because the statute requires that any proposed establishment of an Organized Ambulatory Care Facility be reviewed by the Health Services Council and approved by the state-licensing agency prior to implementation.

Staff reviewed the application, found it to be acceptable in form, and notified the applicant and the general public by a notice on the Department's website and via direct e-mail that the review would commence on January 10, 2018. The notice also advised that all persons wishing to comment on the application submit their comments to the state agency by February 9, 2018, when practicable. No written comments were received.

The Health Services Council met on February 13, 2018 with representatives of the applicant in attendance at the meeting. At the February 13, 2018 meeting the Health Services Council voted seven in favor, none opposed (7-0) to recommend that the application be approved subject to the standard conditions of approval.

IV. FINDINGS

Section 23-17-14.3 of the licensing statute requires the Health Services Council to consider specific review criteria in formulating a recommendation for a change in effective control. The Council's comments and findings on each of the criteria follow:

A. The character, competence, commitment, and standing in the community of the proposed owners, operators or directors of the health care facility.

The applicant stated there are no citations and/or enforcement actions pending and/or involving the applicant and/or its affiliates within the past three years.

According to the applicant, the Center will offer state of the art alternative medicine and dental treatments with a focus on assessing the root causes and promoting the self-healing properties of the body.

The Center stated it is committed to educating the public about the benefits of alternative therapies to traditional medicine and dentistry. The applicant stated it will offer a series of education and awareness campaigns designed for a variety of audiences, who represent all parts of the community.

The Mary Shand Scholarship fund, operated by the Bioregulatory Medicine Institute, a program of the Marion Institute Inc. (a non-profit organization) provides partial financial assistance to clients seeking bioregulatory treatments. Financial assistance is based on urgency of need, financial need and commitment to treatment program. The applicants financial need program is open to people with household incomes up to 500% of the Federal Poverty Guideline.

Finding: The Council finds that, based on the evidence presented and representations made by the applicant, the applicant satisfies this criterion at the time, place and circumstances as proposed.

B. The extent to which the facility will provide, without material effect on its viability, safe and adequate treatment for those individuals receiving the facility's services.

The applicant expects that the Center will operate initially at a loss, but will begin earning a profit by its first full year. Robert Woodford Enterprises, LLC will contribute \$3.6 million (100% equity) to fund the capital and operating needs of the clinic with cash through the clinics parent companies.

The following is projected for facility in FY 2019:

Total Revenues	\$3,328,684
Total Expenses	\$2,917,131
Operating Profit	\$411,553

The Council was not made aware of any other financial concerns related to the implementation of the application.

Finding: The Council finds that, based on the evidence presented and representations made by the applicant, the applicants satisfy this criterion at the time, place and circumstances as proposed.

C. The extent to which the facility will provide safe and adequate treatment for individuals receiving the health care facility's services.

According to the applicant, The Center will establish procedures to ensure quality care to all clients. An ongoing process will be set in place to improve the quality of the organization and its staff through three areas of focus:

- Systemic Quality Improvement
 - Bi-monthly meetings of the Quality Board
 - Meetings to include employees
 - Solicit stakeholder and client input
- Strategic Planning Process
 - Long-term planning goals
 - Short-term planning goals (semi-annual)
 - Data driven outcome measures
 - Quarterly review of Clinical Progress and Documentation
- Employment Utilization
 - Staff development
 - 1:1 training opportunities
 - Retention program
 - Employee participation in strategic planning

- Employee engagement with Board

These areas will be achieved through administrative procedures, internal and external quality assessment, education, data management and in full compliance of all applicable Rhode Island state law.

Finding: The Council finds, based on the evidence presented and representations made by the applicant, that the applicant satisfies this criterion at the time, place and circumstances as proposed.

D. The extent to which the facility will provide appropriate access to traditionally under-served populations.

The following payor mix was projected for the facility if the proposal is approved for FY 2018:

Payor Mix	Percent
Medicare	0%
Medicaid	0%
Blue Cross	5%
Commercial	21%
HMO's	0%
Workers' Comp	0%
Self Pay	74%
Other	0%
Charity Care	0.7%
Total	100%

The bioregulatory services to be offered at the Center are not covered services under Medicare or Medicaid. Some dental services will be covered by insurance, roughly 25%. Those treatments not covered by insurance will be self-pay.

As noted above, the Center stated that it is committed to educating the public about the benefits of alternative therapies to traditional medicine and dentistry. The applicant stated it will offer a series of education and awareness campaigns designed for a variety of audiences, who represent all parts of the community.

The Center plans to develop a bioregulatory certification program in partnership with the Bioregulatory Medicine Network.

The Mary Shand Scholarship fund, operated by the Bioregulatory Medicine Institute, a program of the Marion Institute Inc. (a non-profit organization) provides partial financial assistance to clients seeking bioregulatory treatments. Financial assistance is based on urgency of need, financial need and commitment to treatment program. The applicant stated its financial need program is open to people with household incomes up to 500% of the Federal Poverty Guideline.

Finding: The Council finds that, based on the evidence presented and representations made by the applicant, the applicant satisfies this criterion at the time, place and circumstances as proposed.

V. RECOMMENDATION

After considering each of the review criteria as required by statute and the representations made by the applicant, the Health Services Council recommends that this request for initial licensure be approved.

VI. CONDITIONS OF APPROVAL

The Council recommends that approval of the instant application shall be subject to the following conditions:

1. that the capital costs not exceed \$3,610,657 and be financed with no less than 100% equity
2. that the applicant conducts national background checks on all employees;
3. that the application be implemented as approved;
4. that data, including but not limited to, finances, utilization and demographic patient information, be furnished to the state agency, upon request; and
5. that the applicant provides services to all patients without discrimination including payment source and ability to pay.

The American Center for Bioregulatory Medicine and Dentistry

Project Cost: \$3,610,657

Funding: 100% Equity (Cash) from Robert Woodford Enterprises, LLC

The Applicant

